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Attorneys for Plaintiff
SHIONOGI & CO., LTD.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SHIONOGI & CO., LTD., a Japanese company,

Plaintiff,

v.

INTERMUNE, INC., a Delaware corporation,

Defendant.

Case No.

COMPLAINT FOR BREACH OF CONTRACT, DECLARATORY RELIEF, PROMISSORY ESTOPPEL, UNJUST ENRICHMENT AND ACCOUNTING

DEMAND FOR JURY TRIAL

Plaintiff SHIONOGI & CO., LTD. ("Shionogi") alleges as follows:

I. THE PARTIES

1. Plaintiff Shionogi is, and at all relevant times mentioned herein was, a Japanese company with its principal place of business in Osaka, Japan.

2. Defendant INTERMUNE, INC. ("InterMune") is, and at all relevant times mentioned herein was, a Delaware corporation with its principal place of business in Brisbane, California in San Mateo County.

II. JURISDICTION

3. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332 because Plaintiff Shionogi is citizen of Japan and Defendant InterMune is a citizen of Delaware and/or California, and the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

III. VENUE

4. Pursuant to 28 U.S.C. § 1391(a), venue is proper in this judicial district because Defendant InterMune resides in this judicial district, a substantial part of the events or omissions giving rise to this action occurred in Brisbane, California in San Mateo County, and the contract at issue in this action provides that for "any legal action arising from or related to this Agreement, both parties hereby . . . consent and submit solely to jurisdiction and venue of the state and federal courts located in San Francisco County, California, USA, if initiated by Shionogi."

IV. INTRADISTRICT ASSIGNMENT

5. Pursuant to Northern District of California Local Rule 3-2(d), this action should be assigned to either the San Francisco Division or the Oakland Division because a substantial part of the events or omissions giving rise to this action occurred in Brisbane, California in San Mateo County.

V. ALLEGATIONS

A. The Collaboration Agreement And Amendment

6. Idiopathic Pulmonary Fibrosis ("IPF") is a rare, progressive and fatal lung disease of unknown cause. Plaintiff Shionogi (in Japan, Korea and Taiwan) and Defendant InterMune (in

all other countries of the world) have licenses to develop the chemical compound Pirfenidone for the treatment of IPF and other fibrotic diseases.

7. Effective on or about May 27, 2004, Shionogi and InterMune (together, the "Parties") entered into the Agreement for Collaboration to Exchange Documents from Clinical Studies ("Collaboration Agreement"). Paragraph 6.1 of the Collaboration Agreement provides that it "shall be governed and construed in accordance with the laws of New York, USA."

8. Under the Collaboration Agreement, the Parties agreed to exchange certain documents relating to the Parties' clinical trials of Pirfenidone. The Collaboration Agreement provides that if either Party's documents are to be used as Pivotal Study Data, as that term is defined in the Collaboration Agreement, then the provisions regarding negotiation of an exclusive license under Article 3 of the Collaboration Agreement shall be applied.

9. Effective on or about February 11, 2010, the Parties entered into the First Amendment to Agreement for Collaboration to Exchange Documents from Clinical Studies ("Amendment") (together with the Collaboration Agreement, the "Amended Collaboration Agreement"). In place of the provisions regarding negotiation of a license in Article 3 of the Collaboration Agreement, the Amendment substitutes an exclusive option to acquire an exclusive, royalty bearing license for documents to be used as Pivotal Study Data.

10. The Amendment's royalty provision, which applies upon exercise of the option, provides the following:

> Royalty Payments. As consideration for, and upon grant of, the IPF Exclusive License pursuant to Section 3.4.3, the Grantee shall pay to Grantor during the Royalty Term . . . royalties on Net Sales of Product . . . sold by Grantee, its affiliates or its sublicensees in the Grantee's Respective Territories on a country-by-country basis as follows:
>
> | Years Following Regulatory Approval in the IPF Field | Royalty Percentage |
> |---|---|
> | First calendar year (*) | 6% |
> | Second calendar year | 6% |
> | Third calendar year | 8% |
> | Forth calendar year | 8% |
> | Any subsequent calendar year | 10% |
>
> *First calendar year shall commence on the date of commencement of commercial

sales of the Product (the "Launch Date"), and terminate on December 31st of the year which includes the Launch Date.

11. Also upon exercise of the option, the exclusive licensee obtains the right to additional IPF clinical trial documents, specifically "source data" to which the Parties do not have a right under the Amended Collaboration Agreement absent exercise of the option. Royalty payments under the terms of the exclusive license are not dependent on use of source data.

B. Shionogi's IPF Clinical Trials

12. Plaintiff Shionogi invested tens of millions of dollars in clinical trials of Pirfenidone in Japan from 2000-2006. Shionogi's clinical trials of Pirfenidone included a study referred to as SP2 from 2000-2002 and a study referred to as SP3 from 2004-2006.

13. An objective of SP2 was to investigate the efficacy and safety of Pirfenidone in patients with IPF. It was a multicenter, double-blind, placebo-controlled study.

14. An objective of SP3 was to compare the efficacy and safety of Pirfenidone 1800 mg/day with placebo in patients with IPF. It was also a multicenter, double-blind, placebo-controlled study.

15. Relying on SP2 and SP3, in 2006 Shionogi sought marketing authorization for Pirfenidone from the Japanese Pharmaceuticals and Medical Devices Agency ("PMDA"), and in 2008, the PMDA granted Shionogi authorization to market Pirfenidone in Japan under the trade name Pirespa.

C. InterMune's IPF Clinical Trials

16. InterMune conducted clinical trials of Pirfenidone, including a study referred to as PIPF-004 and a study referred to as PIPF-006 from 2006-2008.

17. An objective of PIPF-004 was to compare the efficacy and safety of Pirfenidone with placebo in patients with IPF.

18. An objective of PIPF-006 was to compare the efficacy and safety of Pirfenidone with placebo in patients with IPF. The primary efficacy analysis of PIPF-006 did not reach statistical significance. The study failed to show that Pirfenidone had an effect on reducing the

rate of decline in the percentage predicted forced vital capacity at 72 weeks, *i.e.*, reducing the rate of decline in lung function.

D. InterMune Obtains An Exclusive License And Uses Shionogi's IPF Clinical Trial Documents As Pivotal Study Data In Its EU Marketing Authorization Application

19. On or about February 26, 2010, InterMune filed a Marketing Authorization Application ("MAA") for Pirfenidone with the European Medicines Agency ("EMA"), which is responsible for the scientific evaluation of medicines developed by pharmaceutical companies for use in the European Union ("EU"). In breach of the Amended Collaboration Agreement, InterMune used Shionogi's IPF clinical trial documents as Pivotal Study Data in its MAA prior to exercising its option to an exclusive license to use Shionogi's IPF clinical trial documents as Pivotal Study Data.

20. In or about May 2010, InterMune belatedly exercised its option to obtain an exclusive license to use Shionogi's IPF clinical trial documents as Pivotal Study Data in the EU ("EU Exclusive License").

21. In addition to the Shionogi IPF clinical trial documents that InterMune already had used as Pivotal Study Data in its EU MAA, after obtaining the EU Exclusive License, InterMune requested and obtained Shionogi's IPF clinical trial "source data" to use as additional Pivotal Study Data. Shionogi's IPF clinical trial "source data" constitutes Shionogi's confidential and valuable proprietary information.

22. InterMune repeatedly sought and obtained Shionogi's advice, consultation and/or assistance in connection with its MAA. Shionogi devoted significant resources to advising, consulting and assisting InterMune in connection with its MAA, including by preparing for EMA's inspection of Shionogi's IPF clinical trials, and preparing InterMune's and Shionogi's responses to EMA's questions relating to Shionogi's IPF clinical trials.

23. In or about December 2010, EMA's Committee for Medicinal Products for Human Use adopted a positive opinion on InterMune's MAA, recommending to the European Commission that it authorize InterMune to market Pirfenidone in the EU under the trade name Esbriet.

24. In or about February 2011 and based on InterMune's MAA that used Shionogi's IPF clinical trial documents as Pivotal Study Data, the European Commission authorized InterMune to market Pirfenidone throughout the EU under the trade name Esbriet.

25. Under the EU Exclusive License and Amended Collaboration Agreement, the European Commission's marketing approval triggered the royalty payment provision, requiring InterMune to pay to Shionogi royalties on InterMune's sales of Esbriet in the EU.

26. From Esbriet's launch in certain EU countries in mid-September 2011 to year-end 2011, InterMune reported unaudited sales of Esbriet of $4.5 million. InterMune reported unaudited sales of Esbriet of $4.9 million for the first quarter of 2012. Shionogi is informed and believes that InterMune continues to sell Esbriet in certain EU countries to the present, plans to continue to sell Esbriet in those countries in the future, and continues to generate revenue from sales of Esbriet in those countries. Shionogi also is informed and believes that InterMune will launch Esbriet in additional EU countries in which sales of Esbriet have not yet occurred and will generate revenue from sales of Esbriet in these additional EU countries.

27. Shionogi has demanded that InterMune pay the royalties due and owing under the EU Exclusive License and Amended Collaboration Agreement, and that InterMune confirm its obligation to pay royalties for future sales of Esbriet in all countries of the EU. InterMune has refused to pay outstanding royalties and repudiated its obligation to pay royalties for future sales of Esbriet in all countries of the EU, thereby injuring and damaging Shionogi.

28. After obtaining an exclusive license to use Shionogi's IPF clinical trial documents as Pivotal Study Data in the EU, using Shionogi's IPF clinical trial documents as Pivotal Study Data in the EU and obtaining marketing approval in the EU, InterMune now claims that it did not use Shionogi's IPF clinical trial documents as Pivotal Study Data in an effort to avoid its obligation to pay royalties to Shionogi. Assuming *arguendo* that its claim is true, InterMune's failure or refusal to use Shionogi's IPF clinical trial documents as Pivotal Study Data is a breach of its duty as an exclusive licensee to exercise reasonable efforts or due diligence to use Shionogi's IPF clinical trial documents as Pivotal Study Data under the EU Exclusive License, thereby injuring and damaging Shionogi.

FIRST CLAIM FOR RELIEF
(Breach Of The Amended Collaboration Agreement And EU Exclusive License)

29. Shionogi repeats and realleges the allegations of paragraphs 1-28, as if fully set forth herein.

30. Shionogi has complied with the terms and conditions of the Amended Collaboration Agreement and the EU Exclusive License, and has fulfilled the obligations on its part to be performed.

31. InterMune has breached its obligations to Shionogi under the Amended Collaboration Agreement and the EU Exclusive License by, among other things:

(a) using Shionogi's IPF clinical trial documents as Pivotal Study Data in its February 26, 2010 MAA in the EU before exercising its option to an exclusive license to use Shionogi's IPF clinical trial documents as Pivotal Study Data in the EU;

(b) failing and refusing to pay the royalties due and owing for sales of Esbriet in those countries of the EU in which sales already have been made;

(c) repudiating its obligation to pay royalties in all countries of the EU where Esbriet will be sold in the future; and/or

(d) failing or refusing to use Shionogi's IP clinical trial documents as Pivotal Study Data in the EU.

32. InterMune at all material times had a duty to act fairly and in good faith and to do nothing which would have the effect of destroying, interfering, frustrating or injuring the rights of Shionogi to receive the benefits of the Amended Collaboration Agreement and the EU Exclusive License.

33. InterMune has breached the implied covenant of good faith and fair dealing that is part of the Amended Collaboration Agreement and the EU Exclusive License by engaging in a course of conduct to deprive Shionogi of its rights under the Amended Collaboration Agreement and the EU Exclusive License. In contravention of its duties and obligations, InterMune has, among other things, destroyed, interfered, frustrated or injured Shionogi's rights by:

(a) unreasonably contending that the belated exercise of its option to an exclusive license after it already had submitted some of Shionogi's IPF clinical trial documents as Pivotal Study Data to the EMA in its MAA establishes that the previously-submitted documents were not used as Pivotal Study Data;

(b) unreasonably contending that it can obtain an exclusive, royalty bearing license to use Shionogi's IPF clinical trial documents as Pivotal Study Data in the EU and have no obligation to exercise reasonable efforts or due diligence to use Shionogi's IPF clinical trial documents as Pivotal Study Data in the EU;

(c) unreasonably contending that InterMune can obtain an exclusive, royalty bearing license to use Shionogi's IPF clinical trial documents as Pivotal Study Data to obtain Shionogi's source data from its IPF clinical trials, which constitute Shionogi's confidential and valuable proprietary information, without an intention to use Shionogi's IPF clinical trial documents as Pivotal Study Data;

(d) unreasonably contending that Shionogi is required to expend substantial resources supporting InterMune's MAA, and providing documents and analysis without receiving the benefits of the Amended Collaboration Agreement and the EU Exclusive License;

(e) unreasonably contending that the royalty provisions of the Amendment Collaboration Agreement and the EU Exclusive License apply only to "patient level data" when the royalty provisions apply to any and all IPF clinical trial documents used as Pivotal Study Data; and

(f) unreasonably contending that it now holds an EU Exclusive License to all of Shionogi's IPF clinical trial documents, which Shionogi can no longer use or license in the EU, and for which Shionogi may not collect a royalty.

34. InterMune did the things and committed the acts alleged above for the purpose of consciously withholding from Shionogi the rights and benefits to which it is entitled under the Amended Collaboration Agreement and the EU Exclusive License.

35. As a direct and proximate result of InterMune's breach of the Amended Collaboration Agreement and EU Exclusive License as well as the implied covenant of good faith

and fair dealing that is part of every contract, including the Amended Collaboration Agreement and EU Exclusive License, Shionogi has been injured and damaged in an amount to be proven at trial, but in an amount that exceeds the sum of $75,000, exclusive of interest and costs.

SECOND CLAIM FOR RELIEF
(Declaratory Relief Regarding The Parties' Respective Rights And Duties Under The Amended Collaboration Agreement And EU Exclusive License)

36. Shionogi repeats and realleges the allegations of paragraphs 1-35, as if fully set forth herein.

37. InterMune is obligated under the Amended Collaboration Agreement and EU Exclusive License to pay royalties for sales of Esbriet in all countries of the EU. Royalties are due and owing under the Amended Collaboration Agreement and EU Exclusive License because, among other reasons, InterMune obtained an exclusive license to use any or all of Shionogi's IPF clinical trial documents as Pivotal Study Data in the EU and/or InterMune used Shionogi's IPF clinical trial documents as Pivotal Study Data in its MAA, and the European Commission granted marketing approval for Esbriet. InterMune disagrees.

38. Under the Amended Collaboration Agreement, whether IPF clinical trial documents are to be used as Pivotal Study Data is dependent on the Party's conduct and independent of a regulatory authority's use or analysis of the IPF clinical trial documents. InterMune disagrees.

39. Under the Amended Collaboration Agreement, a Party's exercise of the exclusive option to acquire an exclusive, royalty bearing, right and license to use the other Party's IPF clinical trial documents as Pivotal Study Data in a particular geographical area is a contractual agreement to exercise reasonable efforts or due diligence to use the other Party's IPF clinical trial documents as Pivotal Study Data in that particular geographical area. InterMune disagrees.

40. By reason of the foregoing, an actual controversy presently exists between Shionogi and InterMune. Accordingly, Shionogi seeks a declaration that:

(a) InterMune is obligated to pay royalties on all sales of Esbriet in the EU;

(b) whether IPF clinical trial documents are to be used as Pivotal Study Data by a Party to the Amended Collaboration Agreement is dependent on the Party's conduct and independent of a regulatory authority's use or analysis of the IPF clinical trial documents; and/or

(c) a Party's exercise pursuant to the Amended Collaboration Agreement of the exclusive option to acquire an exclusive, royalty bearing, right and license to use the other Party's IPF clinical trial documents as Pivotal Study Data in a particular geographical area is an agreement to exercise reasonable efforts or due diligence to use the other Party's IPF clinical trial documents as Pivotal Study Data in that particular geographical area.

THIRD CLAIM FOR RELIEF
(Promissory Estoppel)

41. Shionogi repeats and realleges the allegations of paragraphs 1-40, as if fully set forth herein.

42. InterMune promised to use and to pay Shionogi for InterMune's use of Shionogi's IPF clinical trial documents as Pivotal Study Data in connection with InterMune's MAA in the event InterMune obtained authorization to market Pirfenidone in the EU.

43. Shionogi reasonably relied on those promises in providing certain documents relating to its clinical trials of Pirfenidone to InterMune, including but not limited to certain of its confidential and valuable proprietary information from its IPF clinical trials, and investing time and resources in providing its IPF clinical trial documents and responding to InterMune and EMA questions regarding Shionogi's IPF clinical trial documents.

44. As a direct and proximate result of InterMune's conduct, Shionogi has been damaged and injured due to its reliance on InterMune's promise to use and to pay for its use of Shionogi's IPF clinical study documents as Pivotal Study Data in InterMune's MAA by, among other damages, the loss of Shionogi's ability to license its IPF clinical trial documents in the EU, the costs incurred by Shionogi in providing its IPF clinical trial documents and cooperating with InterMune in responding to InterMune's and EMA's questions regarding Shionogi's IPF clinical trial documents and preparing for inspection, the loss of Shionogi's exclusive possession and control of certain of its IPF clinical trial documents, which constitute Shionogi's confidential and

valuable proprietary information, and the loss of the royalties InterMune promised to pay on sales of Pirfenidone in the EU.

FOURTH CLAIM FOR RELIEF
(Unjust Enrichment)

45. Shionogi repeats and realleges the allegations of paragraphs 1-44, as if fully set forth herein.

46. Shionogi provided InterMune with IPF clinical trial documents, including but not limited to documents that constituted Shionogi's confidential and valuable proprietary information, and invested time and resources in providing its IPF clinical trial documents and responding to InterMune and EMA questions regarding Shionogi's IPF clinical trial documents.

47. Due, at least in part, to InterMune's use of Shionogi's IPF clinical trial documents in its MAA and Shionogi's investment of time and resources in providing documents and responding to InterMune and EMA inquiries, InterMune obtained authorization to market Pirfenidone in the EU under the trade name Esbriet yet now refuses to pay Shionogi for its use of Shionogi's IPF clinical trial documents or to return Shionogi's confidential and valuable proprietary information.

48. InterMune unjustly benefitted at Shionogi's expense because, among other reasons, the EU Exclusive License precludes Shionogi from licensing its IPF clinical trial documents to any other person in the EU, caused Shionogi to incur costs in providing its IPF clinical trial documents and cooperating with InterMune in responding to InterMune's and EMA's questions regarding Shionogi's IPF clinical trial documents and preparing for inspection, and caused Shionogi to lose exclusive possession and control of certain of its IPF clinical trial documents constituting Shionogi's confidential and valuable proprietary information.

49. InterMune is thereby unjustly enriched at Shionogi's expense and equity and good conscience requires that InterMune provide damages and/or restitution, and return Shionogi's confidential and valuable proprietary information.

FIFTH CLAIM FOR RELIEF
(Accounting)

50. Shionogi repeats and realleges the allegations of paragraphs 1-49, as if fully set forth herein.

51. On or about May 2004, Shionogi and InterMune entered into the Collaboration Agreement and, on or about February 2010, the Amended Collaboration Agreement, under which the Parties entrusted to each other certain of their respective IPF clinical trial documents, which if used by the other Party as Pivotal Study Data entitled the Party providing the IPF clinical trial documents to royalties. As such, there was a fiduciary or trust relationship between Shionogi and InterMune requiring each to account to the other for the royalties resulting from the use of other's IPF clinical trial documents.

52. Pursuant to the Amended Collaboration Agreement, on or about May 2010, InterMune exercised its exclusive option, whereby Shionogi and InterMune entered into the EU Exclusive License. Under the EU Exclusive License, InterMune undertook the obligation to use Shionogi's IPF clinical trial documents as Pivotal Study Data in InterMune's MAA filed in the EU, and InterMune did, in fact, use Shionogi's documents as Pivotal Study Data. InterMune's obligations under the EU Exclusive License included the duty, during the royalty term, to pay to Shionogi royalties on InterMune's "Net Sales" of Esbriet in the EU in accordance with the royalty percentages provided in the EU Exclusive License. As such, there was a fiduciary or trust relationship between Shionogi and InterMune, requiring InterMune to account to Shionogi for InterMune's "Net Sales" of Esbriet in the EU.

53. Since obtaining authorization to market Esbriet in the EU, InterMune has made sales of Esbriet within the EU and has received money, a portion of which is due to Shionogi pursuant to the terms of the EU Exclusive License and/or Amended Collaboration Agreement.

54. The amount of money due from InterMune to Shionogi is unknown to Shionogi and cannot be ascertained without an accounting of the "Net Sales," as defined under the EU Exclusive License and/or Amended Collaboration Agreement, of Esbriet, which information is

solely in the possession of InterMune. Shionogi is informed and believes and thereon alleges that the amount owed, however, exceeds the sum of $75,000, exclusive of interest and costs.

55. Shionogi has demanded that InterMune account for the aforementioned "Net Sales" of Esbriet in the EU, and pay the amount found due to Shionogi, but InterMune has failed and refused, and continues to fail and refuse, to render the accounting and pay Shionogi.

VI. PRAYER FOR RELIEF

WHEREFORE, Shionogi requests this Court to enter a judgment as follows:

A. With respect to the First Claim for Relief, for damages against InterMune according to proof at the time of trial, including reasonable attorneys' fees and costs, plus interest and/or specific enforcement or a permanent injunction.

B. With respect to the Second Claim for Relief, a declaration that:

(a) InterMune is obligated to pay royalties on all sales of Esbriet in the EU;

(b) whether IPF clinical trial documents are to be used as Pivotal Study Data by a Party to the Amended Collaboration Agreement is dependent on the Party's conduct and independent of a regulatory authority's use or analysis of the IPF clinical trial documents; and/or

(c) a Party's exercise pursuant to the Amended Collaboration Agreement of the exclusive option to acquire an exclusive, royalty bearing, right and license to use the other Party's IPF clinical trial documents as Pivotal Study Data in a particular geographical area is an agreement to exercise reasonable efforts or due diligence to use the other Party's IPF clinical trial documents as Pivotal Study Data in that particular geographical area.

C. With respect to the Third Claim for Relief, for damages and/or restitution from InterMune according to proof at the time of trial, including reasonable attorneys' fees and costs, plus interest.

D. With respect to the Fourth Claim for Relief, for damages and/or restitution from InterMune according to proof at the time of trial, including reasonable attorneys' fees and costs, plus interest, and an order directing the return of Shionogi's confidential and valuable proprietary information.

E. With respect to the Fifth Claim for Relief, for an accounting between Shionogi and InterMune for payment to Shionogi of the amount due from InterMune as a result of the account, including reasonable attorneys' fees and costs, plus interest.

F. With respect to all claims for relief, such other relief as the Court may deem just and proper.

Dated: July 5, 2012

Jones Day

By: _____
Jason McDonell

Attorneys for Plaintiff
SHIONOGI & CO., LTD.

VII. DEMAND FOR JURY TRIAL

Plaintiff Shionogi & Co., Ltd. demands a jury trial for all issues and causes of action for which it is entitled to a jury trial.

Dated: July 5, 2012

Jones Day

By: _____
Jason McDonell

Attorneys for Plaintiff
SHIONOGI & CO., LTD.

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